Supreme Court, U. S.
FILED
SEP 5 1975
MICHAEL RODAK, JR., CLERK

IN THE

Supreme Court of the United States

OCTOBER TERM, 1975

No. 75-3614

ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, ET AL.,

Appellants,

vs.

F. DAVID MATHEWS, Secretary of Health, Education and Welfare,

Appellee.

On Appeal from the United States District Court for the Northern District of Illinois

JURISDICTIONAL STATEMENT

R. R. McMAHAN
135 S. LaSalle Street
Chicago, Illinois 60603
Attorney for Appellants

LORD, BISSELL & BROOK
135 S. LaSalle Street
Chicago, Illinois 60603
Of Counsel

Midwest Law Printing Co., Chicago 60601, Financial 6-3988

INDEX

	PAGE
Jurisdictional Statement	1
Opinion Below	2
Jurisdiction	2
Questions Presented	2
Statutes Involved	3
Statement	4
The Questions Are Substantial	9
Conclusion	21
Appendix A	1a
Appendix B	2a
Appendix C	31a
Appendix D	33a

CITATIONS

Cases

Abele v. Markle, 452 F.2d 1121 (2nd Cir. 1971)	18
American Medical Ass'n, et al. v. Weinberger, ... F.2d ..... (7th Cir. Docket No. 75-1547, July 22, 1975)	10, 11, 12
Aptheker v. Secretary of State, 378 U.S. 500 (1964)	15, 16
Connally v. General Construction Co., 269 U.S. 385 (1926)	20

Dent v. West Virginia, 129 U.S. 114 (1889) 10, 16
Doe v. Bolton, 410 U.S. 179 (1973) 16, 17, 18
Doe v. Dunbar, 320 F.Supp. 1297 (D.C. Colo. 1970) 18
Doe v. Scott, 321 F.Supp. 1385 (N.D. Ill. 1971) 10, 18
Frost Trucking Co. v. Railroad Comm'n, 271 U.S. 583 (1926) 15
Giaccio v. Pennsylvania, 382 U.S. 399 (1966) 21
Griswold v. Connecticut, 381 U.S. 479 (1965) 10, 16, 18
Lanzetta v. New Jersey, 306 U.S. 451 (1939) 20, 21
Lefkowitz v. Turley, 414 U.S. 70 (1973) 15, 16
Memorial Hospital v. Maricopa County, 415 U.S. 250 (1974) 15
Meyer v. Nebraska, 262 U.S. 390 (1923) 16
Nyberg v. City of Virginia, 495 F.2d 1342 (8th Cir. 1974) 18
Poe v. Menghini, 339 F.Supp. 986 (D.C. Kan. 1972) .. 16, 17
Reed v. Gardner, 261 F.Supp. 87 (C.D. Calif. 1966) 18
Richardson v. Belcher, 404 U.S. 78 (1971) 15
Roe v. Ingraham, 364 F.Supp. 536 (S.D.N.Y. 1973) 18
Roe v. Wade, 410 U.S. 113 (1973) 10, 16
Shapiro v. Thompson, 394 U.S. 618 (1969) 16
Shelton v. Tucker, 364 U.S. 479 (1960) 16
Sherbert v. Verner, 374 U.S. 398 (1963) 15, 16
Small Co. v. American Sugar Ref. Co., 267 U.S. 233 (1925) 21

Speiser v. Randall, 357 U.S. 513 (1958) 17
Steward Machine Co. v. Davis, 301 U.S. 548 (1937) 14
Thorpe v. Housing Authority, 386 U.S. 670 (1967) 16
United States v. Chicago, etc., R. Co., 282 U.S. 311 (1931) 15
United States v. National Dairy Products Corp., 372 U.S. 29 (1963) 21
United States v. Vuitch, 402 U.S. 62 (1971) 17
U.S. Dep't of Agriculture v. Moreno, 413 U.S. 528 (1973) 15
U.S. Dep't of Agriculture v. Murry, 413 U.S. 508 (1973) 15
U.S. v. Robel, 389 U.S. 258 (1967) 16
Wulff v. Singleton, 508 F.2d 1211 (8th Cir. 1975) 18
YWCA of Princeton v. Kugler, 342 F.Supp. 1048 (D.C. N.J. 1972) 18, 20

Statutes

Title 42 United States Code
Section 1320c 4
Section 1320c-1 5
Section 1320c-4 5
Section 1320c-4(a) 7
Section 1320c-4(a)(1) 5
Section 1320c-4(a)(2) 6
Section 1320c-4(a)(4) 6
Section 1320c-5(b) 5
Section 1320c-5(d) 6
Section 1320c-8 7

Section 1320c-9(a) 6
Section 1320c-9(a)(2) 19
Section 1320c-9(b)(1) 19
Section 1320c-9(b)(1)(A) 7
Section 1320c-9(b)(1)(B) 7
Section 1320c-9(b)(1)(C) 19
Section 1320c-9(b)(3) 7, 19
Section 1320c-19 4
Section 1395 4
Section 1395d 13
Section 1395k 13
Section 1395pp 4
Section 1396 4
Section 1396i 4

Congressional and Miscellaneous

Senate Finance Committee Report on H.R. 1, 92nd Cong. 2nd Sess., Sen. Rep't No. 92-1320 (Sept. 26, 1972) 5

Decker & Bonner (eds), PSRO: *Organization for Regional Peer Review* (Ballinger, 1973) 9, 13

Medicare Hospital Manual (HIM 10) Sec. 290 14

In The

Supreme Court of the United States

October Term, 1975

No.

ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, ET AL.,

Appellants,

vs.

F. DAVID MATHEWS, Secretary of Health, Education and Welfare,

Appellee.

On Appeal from the United States District Court for the Northern District of Illinois

---

JURISDICTIONAL STATEMENT

Appellants appeal from the judgment order of the United States District Court for the Northern District of Illinois entered on May 8, 1975, denying the injunctive and declaratory relief prayed for in their complaint. A copy of the Court's order is reproduced herein as Appendix A. Appellants submit this statement to show that the Supreme Court of the United States has jurisdiction of this appeal and that substantial questions are presented.

OPINION BELOW

The Memorandum Opinion of the District Court for the Northern District of Illinois is reported at 395 F.Supp. 125, and is reproduced herein as Appendix B.

JURISDICTION

This action was brought under 28 USC §1331 to enjoin the implementation and enforcement of certain provisions of the Social Security Amendments of 1972 on the ground that they are repugnant to appellants' rights under the Constitution of the United States. The action was heard and determined by a district court of three judges under 28 USC §2284 as required by 28 USC §2282. On May 8, 1975, the district court dismissed the action for failure to state a claim upon which relief could be granted, notice of appeal to this Court (Appendix C hereto) was filed on July 7, 1975. The jurisdiction of the Supreme Court to review this decision on direct appeal is conferred by 28 USC §1253.

QUESTIONS PRESENTED

1. Did appellants state a cognizable claim for violation of their constitutional rights and the constitutional rights of their patients when they alleged in the District Court that the legislation in question unduly interferes with their right to practice their profession, that it would seriously impair their right to render, and their patients' right to receive medical care in accordance with their own best professional judgment, and that it would invade the privacy of the physician-patient relationship with consequent detriment and hindrance to their patients' well being?

2. Did the District Court err in dismissing appellants' complaint on the grounds that the legislation in question amounted merely to regulation of expenditures under a voluntary government program, without considering appellants' charge that the law imposed unconstitutional conditions upon their participation, and the participation of elderly and indigent patients, in the program?

3. Did the District Court err in refusing to require the Government to justify this legislation's invasion of fundamental rights of appellants and their patients by showing that the legislation served a compelling state interest and that its sweep was not arbitrarily or unnecessarily broad?

4. Did the District Court adequately and accurately review those provisions of the law alleged by appellants to be unconstitutionally vague, and did the court properly interpret the precedents of this Court governing such review in reaching its conclusion that appellants' allegations of statutory vagueness failed to state a claim upon which relief could be granted?

STATUTES INVOLVED

Section 249F(b) of the Social Security Amendments of 1972, October 30, 1972, Pub. L. 92-603, Title II, §249F(b), 86 Stat. 1429; 42 USC §§1320c, *et seq.*, the relevant provisions of which are set out in Appendix D hereto.*

* For clarity and convenience of reference, the provisions of this legislation will be cited herein as they appear in Title 42 of the United States Code.

STATEMENT

The appellants in this case are an association of physicians, representing the interests of its members, and three individual physicians,[1] (not members of the association), whose treatment of patients eligible for benefits under the federal Medicare[2] and Medicaid[3] programs will be substantially affected by the extensive requirements, obligations and restraints imposed by the provisions for "Professional Standards Review" (42 USC §§1320c through 1320c-19) which Congress added to Title XI of the Social Security Act in 1972.[4]

In June of 1974, appellants filed suit in the U.S. District Court for Northern District of Illinois to enjoin en-

[1] They are: Dr. Roy R. Grinker, Sr., Chairman of the Department of Psychiatry of Chicago's Michael Reese Hospital and Director of that hospital's Institute for Psychosomatic and Psychiatric Research and Training, and Professor of Psychiatry in the University of Chicago's Pritzker School of Medicine; Dr. George E. Shambaugh, Jr., Professor of Otolaryngology, Northwestern University Medical School, Chicago, member of the attending staff of Northwestern Memorial Hospital, and of the consulting staff of Henrotin Hospital, both in Chicago; Dr. Edward A. Wolpert, Director of clinical services of the Michael Reese Hospital's Institute for Psychosomatic and Psychiatric Research and Training, Clinical Associate Professor of Psychiatry in the Pritzker School of Medicine and Consultant to the Sonia Shankman Orthogenic School, both of the University of Chicago.

[2] 42 USC §§1395 through 1395pp.

[3] 42 USC §§1396 through 1396i.

[4] Section 249F(b) of Title II of the "Social Security Amendments of 1972", Oct. 30, 1972, Pub. L. 92-603; 86 Stat. 1429.

forcement of these provisions on the ground that the scheme of regulation of medical practice created by the legislation violated their rights and the rights of their patients under the federal Constitution in several major respects.

The Professional Standards Review law represents a congressional attempt to achieve cost savings in the Medicare and Medicaid programs (see App. B, pp. 3a-4a) by assuming control over, and imposing federal standards and limitations on, the manner in which private physicians diagnose, treat, and care for patients who are beneficiaries under these programs. The Secretary of Health, Education and Welfare is to divide the nation into geographic regions and designate for each a "Professional Standards Review Organization" (PSRO)[5] which is to maintain surveillance over the activities of physicians and institutions providing health care services under the Social Security Act. 42 USC §§1320c-1, 1320c-4. The PSROs are to use a system of pre-set regional "norms" describing what is to be considered "appropriate" diagnosis and treatment of particular illnesses and health conditions, 42 USC §1320c-5(b), to determine whether the services rendered by a physician (or a hospital) are "medically necessary" and carried out in the most economical facility. 42 USC §1320c-4(a)(1). They are charged with policing, in accordance with

[5] PSROs must be composed of medical practitioners until the end of 1975, 42 USC §1320c-1; thereafter their functions may, if necessary, be performed by any group or organization chosen by the Secretary of HEW. PSROs could be composed of personnel from state and local health departments, medical schools, insurance carriers and intermediaries, or other health insurers. Senate Finance Committee Report on H.R. 1, 92nd Cong. 2nd Sess., Sen. Rep't No. 92-1320 (Sept. 26, 1972).

federal regulations, the length of time a patient stays in a hospital, 42 USC §1320c-5(d), and are authorized to determine in advance, on a case-by-case basis, whether any elective admission to a hospital, or any other health care service that may consist of extended or costly courses of treatment, would meet the criteria of the law if rendered by a particular physician or institution. 42 USC §1320c-4(a)(2).

The PSROs also are charged with enforcing the substantial obligations imposed upon practicing physicians by the law. Physicians are required to assure that items or services ordered for Social Security beneficiaries and recipients are consistent with the normative criteria of diagnosis, treatment and care established under the law, and must stand prepared to prove that to be the case ". . . by evidence of such medical necessity and quality in such form and fashion and at such time as may reasonably be required . . ." by a PSRO. 42 USC §1320c-9(a). The law also charges practitioners with a broad responsibility for governing the conduct of others. They are required to assure to the extent of their influence or control over others dealing with their patients, that no other physician, or hospital or agency, or any person, including the patient himself, will violate the requirements and standards of the law. 42 USC §1320c-9(a). In aid of the detection of departures from the law, the PSROs will maintain ongoing "profiles" of physicians, showing the care and services rendered, and of patients, showing care and services received. 42 USC §1320c-4(a)(4).

PSROs are empowered to disapprove health care services and items provided by a physician to a Social Security

beneficiary. 42 USC §1320c-4(a).[6] Under this section the PSRO may also disapprove in advance any elective admission to a hospital or other health care facility for treatment not meeting the requirements of the law, or on the ground that the particular elective treatment proposed would not meet the law's criteria if rendered by the particular physician proposing it.

If the Secretary of HEW finds, upon a charge made by a PSRO, that a physician has ". . . demonstrated an unwillingness or a lack of ability substantially to comply with such obligation . . .", he may, in addition to any other sanction provided under law, ". . . exclude (permanently or for such period as the Secretary may prescribe) such practitioner . . . from eligibility to provide such services on a reimbursable basis." An "unwillingness" or "lack of ability" to comply with these obligations is to be inferred from a physician's failure in a substantial number of cases, substantially to comply with an obligation imposed by the law, or from gross and flagrant violation of any such obligation in one or more instances. 42 USC §1320c-9(b)(1)(A) and (B). In lieu of this sanction, the Secretary may require as a condition of continued eligibility under the law, that a physician pay to the United States the cost of the services found unnecessary or improper, up to $5000. 42 USC §1320c-9(b)(3).

---

[6] A beneficiary, recipient, or practitioner who is dissatisfied with a determination made by a PSRO in its exercise of the powers described above is entitled to have the PSRO "reconsider" its own decision. If the PSRO reaffirms itself, and if it is situated in a state that happens to have an optional state-wide review council in operation, and if the amount in controversy is $100 or more, that body can review the determination, and its decision is reviewable by the Secretary. 42 USC §1320c-8. The statute, however, provides no recourse from determinations of a PSRO in matters involving less than $100.

Appellants alleged in the court below that they are physicians subject to the legal burdens and obligations described above, that they are professionally competent medical practitioners of good moral character who have patients who are Social Security recipients or beneficiaries, and that in administering to these patients each makes his decisions concerning diagnosis, treatment and care solely in accordance with his best medical judgment of the patient's best interests—as his training, experience and skills dictate in the circumstances of each case. They further alleged that subjecting their professional judgments and conduct to prior and concurrent restraints on the basis of any system of pre-set norms of diagnosis, treatment and care would seriously impair their ability to render, and their patients' ability to receive health care in accordance with the highest standards of medical practice. They alleged that under this law their patients could be denied treatment appellants judged necessary, or be required to obtain such treatment from a physician other than the one of their choice. They alleged that the obligations imposed upon them to maintain and disclose information concerning their patients would interfere with the privacy and confidentiality of their relationship with patients which is necessary to foster the full and candid communication between physician and patient essential to diagnosis and treatment. Finally, they alleged that they would be deterred and hindered in advising and treating their patients by the chilling effect of the law's coercive sanctions and the irreconcilable conflict between their duty to patients and their duty to the government that the law creates.

The government responded to the complaint with a motion for summary judgment, which the district court treated as a motion to dismiss and, presumably viewing the

factual allegations of the complaint as true for purposes of the motion as it must, found that they failed to state a claim upon which relief could be granted. (App. B, p. 3a).

THE QUESTIONS ARE SUBSTANTIAL

The legislation in question signals the first extension of federal authority to the control of the substantive aspects of medical practice through the imposition of prior and concurrent restraints upon physicians' professional medical judgments and practices in treating their patients. Enacted to control expenditures under the federal Medicare and Medicaid programs, the law represents a radical departure from traditional concepts of case-by-case, after the fact, professional peer review[7] and the assurance of highest quality medical care such review fosters. Millions of elderly and indigent persons entitled to benefits under the Medicare-Medicaid programs, and the hundreds of thousands of physicians who care for their health will be affected by the

[7] See Decker & Bonner (eds), PSRO: Organization for Regional Peer Review 14 (Ballinger, 1973):

> Consultation and teaching or supervisory rounds are the oldest and simplest form of peer review. Such one-to-one review is generally concurrent, has a formative role in patient care, and depends upon the application of implicit criteria by a recognized expert. Within hospitals, the responsibility for peer review has been delegated to the medical staff, a particular service, its chief, or a designated committee. Collectivity has enlarged the scope of review and introduced retrospective methods geared to prospective educational solutions. Nevertheless, until recently, hospital peer review has also depended upon the application of implicit criteria by recognized experts.

broad regulatory scheme created by the Professional Standards Review law.

1. In the instant litigation, a federal court was asked to consider for the first time whether continuous national administrative direction, regulation, and control of a physician's judgments concerning the diagnosis, treatment and care of his patients unduly interferes with the constitutionally protected rights of both physicians and patients which this Court has recognized are inherent in that relationship. See *Doe* v. *Bolton*, 410 U.S. 179 (1973); *Roe* v. *Wade*, 410 U.S. 113 (1973); *Griswold* v. *Connecticut*, 381 U.S. 479 (1965); *Dent* v. *West Virginia*, 129 U.S. 114 (1889). The court below failed to recognize the constitutional dimensions of the issues raised in appellants' complaint. Rather, it summarily dismissed the action out of the erroneous belief that the legislation in question merely constituted a regulation of the dispensation of federal funds about which physicians could have no cause to complain because they are free to forego treating patients who are beneficiaries under the Medicare-Medicaid programs.

Since the decision below, the Court of Appeals for the Seventh Circuit has reached a contrary result in a case involving the same constitutional issues. *American Medical Ass'n, et al.* v. *Weinberger*, ... F.2d ..... (Docket No. 75-1547, decided July 22, 1975.) In that case, the American Medical Association, along with five individual physicians and eleven patients, sued to enjoin the Secretary of H.E.W. from enforcing regulations requiring review within 24 hours of the necessity for a hospital admission on the grounds, *inter alia*, that the regulations constituted an unwarranted and dangerous interference with a physician's constitutional right to practice medicine and the constitutional right of their patients to receive medical treatment in accordance with the best professional judgment of their physicians.

In the *AMA* case neither the district court nor the court of appeals felt, as did the court below in the instant case, that the plaintiffs *were not entitled to a hearing* because the regulations merely governed the dispensation of federal funds under a program they were free not to participate in.[8] Indeed, the district court issued a preliminary injunction in favor of the plaintiffs, and the court of appeals upheld it. The court of appeals in the *AMA* case, unlike the district court in the instant case, recognized that the plaintiffs had stated a claim for violation of their constitutional rights upon which they deserved a hearing:

> In *Doe* v. *Bolton*, 410 U.S. 179 (1973), the Supreme Court concluded that requiring approval of a licensed physician's medical decisions violates the constitutional rights of both physicians and patients. Also see *Griswold* v. *Connecticut*, 381 U.S. 479 (1965); *Rosen* v. *Louisiana State Board of Medical Examiners*, 380 F. Supp. 875 (E.D. La. 1974), *aff'd* 42 L.Ed.2d 795 (1975); *Nyberg* v. *City of Virginia*, 495 F.2d 1342 (8th Cir.

---

[8] These regulations represent a partial implementation of review procedures which ultimately are to be enforced by PSROs under the scheme of regulation created by the legislation in question in this case, and the injunction issued in the *AMA* case directly affects the PSRO program. As the Court of Appeals noted (slip opinion p. 7):

> There is no doubt that there is a substantial public interest question involved in this litigation. The regulations play an integral and critical role in two nation-wide programs of substantial magnitude.
>
> • • • • •
>
> The injunction places in limbo the efforts of H.E.W. to foster the establishment of Professional Service [sic] Review Organizations (PSROs) across the country.

1974), *cert. denied* 42 L.Ed.2d 136. Whether the *Doe* decision and the other cases cited are really applicable to the instant case is a question that can only be answered after trial. [Slip opinion p. 5 fn. 7]

The court of appeals went on to observe that ". . . the public interest demands that any assertion of constitutional rights, *quite apart from the rights of the magnitude at issue in this proceeding,* be adjudicated in an orderly, principled and judicious manner" (slip opinion p. 8; emphasis added), and that "a reading of the arguments addressed to the substantive question of whether the new regulations violated the constitutional rights of patients and doctors shows a collection of very substantial and difficult legal questions" (slip opinion pp. 8-9). The court concluded that its ". . . review of the case, as presented thus far, leaves us with the impression that plaintiffs could ultimately succeed". (slip opinion p. 9).

Appellants submit that the differing views of the court below in this case and the court of appeals in the *AMA* case concerning the constitutional implications of allegations of undue interference with the physician-patient relationship represents a decisional conflict warranting review and resolution by this Court.

2. The district court's conclusion that appellants' complaint failed to state *any* claim for relief is based principally on the profoundly misconceived notion that the legislation in question was enacted merely to provide "standards for the dispensation of Federal funds" to physicians (App. B, pp. 11a, 15a-16a), the strictures of which they are free to endure or not as they see fit, and that, consequently any question as to its constitutionality is laid to rest merely by a determination that the law is reasonable in relation to its subject matter and does not create discriminations that are patently arbitrary or totally lacking in rational justification. (App. B, p. 11a).

It is important to note at the outset that the district court has misunderstood the role of physicians in the Medicare-Medicaid programs. Physicians do not receive payment under these programs as public contractors or employees, and their participation in the programs does not constitute a submission to any of the regulatory authority commonly incident to such contractual arrangements. Benefits under the Social Security Act are payable to, or on behalf of, the persons eligible for them. 42 USC §§1395d, 1395k. It also is important to realize that physicians will not be able, in any meaningful sense, to avoid the impact of the law by refusing to treat Medicare-Medicaid beneficiaries, as the district court appeared to believe. (App. B, p. 15a). The PSRO law applies to hospitals and all other providers of health care with which a practicing physician must deal. These institutions cannot as a practical matter institute and maintain two different programs of control and surveillance—one to satisfy the requirements of the law and the other for private patients. The law encourages application of its provisions to all patients in these institutions, and all physicians using the facilities of such an institution, of course, would be required to comply with its requirements regardless of who his patient might be.[9]

---

[9] A study conducted for the Community Health Service of the Department of Health, Education and Welfare (Decker & Bonner, Note 7 *supra* at p. 11 accurately sums up the practical impact of the PSRO law:

> Legal constraints, public demands, and professional attitudes make it impossible to justify two standards of medical care in

(footnote continued on following page)

The court below satisfied itself as to the constitutionality of this legislation with the observation that since ". . . each individual physician and practitioner has the ability to choose whether to participate in the program" (App. B, p. 15a) ". . . the statute does not act upon the plaintiffs in such a mandatory fashion as to amount to an unconstitutional interference with plaintiffs' right to practice" (App. B, p. 16a). As its sole authority for this proposition, the court relied upon *Steward Machine Co.* v. *Davis*, 301 U.S. 548, 589-590 (1937), a case involving the arcane question of whether a federal tax credit designed to induce states to enact unemployment compensation systems constituted an invasion of the residual states' rights mentioned in the Tenth Amendment. The court completely disregarded the decisions of this Court that truly are pertinent to the issue—those decisions clearly and flatly holding that participation in, or access to, so-called public "privileges" or "benefits" may not be *conditioned upon* an individual's surrender of his constitutional rights. See *Lef-*

---

our contemporary society. The consulting panel understood P.L. 92-603 to mandate professional review only for the beneficiaries of the Social Security Act. More importantly, the panel appreciated that this restriction, except in terms of dollar support for the activity, is literally impossible. The norms of care and most of the forms of professional audit developed for federal beneficiaries under PSRO, will ultimately be applied to all private medical services. In addition to their inherent resistance to separating "federal care" from "medical care," as evidenced by the common extension of utilization review to private hospital care, physicians are aware of the public and legal pressures to extend PSRO norms and reviews to the entire private health delivery system.

The Secretary of H.E.W. virtually has guaranteed this result as a matter of economics by providing that physicians who serve on hospital utilization review committees will not be paid for their service unless the review plan applies to all of the hospital's in-patients. *Medicare Hospital Manual* (HIM 10) Sec. 290.

kowitz v. *Turley*, 414 U.S. 70, 82-83 (1973) ("A waiver [of Fifth Amendment rights] secured under threat of substantial economic sanction [ineligibility for public contracts] cannot be termed voluntary"); *Aptheker* v. *Secretary of State*, 378 U.S. 500, 507 (1964) ("The restrictive effect of the legislation cannot be gainsaid by emphasizing as the Government seems to do, that a member of a registering [Communist] organization could recapture his freedom to travel by simply . . . abandoning his membership in the organization"); *Sherbert* v. *Verner*, 374 U.S. 398, 405 (1963); *United States* v. *Chicago, etc., R. Co.*, 282 U.S. 311, 328 (1931); *Frost Trucking Co.* v. *Railroad Comm'n*, 271 U.S. 583, 593 (1926).

3. The district court's finding that the cost control measures of the PSRO law are within the competency of the federal government because of its "extensive presence" in the health care field, and that such measures are not arbitrary or totally lacking in rationality (App. B, p. 28a) does not begin to justify the court's dismissal of appellants' claim that this scheme of regulation constitutes an overbroad interference with their rights and the rights of their patients that is unwarranted by any compelling public interest. The fact that a congressional enactment deals only with the regulation of the dispensation of public benefits does not render it immune to charges of unconstitutional arbitrariness or overbreadth. See *U.S. Dep't of Agriculture* v. *Murry*, 413 U.S. 508 (1973); *U.S. Dep't of Agriculture* v. *Moreno*, 413 U.S. 528 (1973); *Richardson* v. *Belcher*, 404 U.S. 78, 81 (1971). When it is alleged—as it is alleged in this case—that such legislation interferes with rights considered fundamental under the Constitution, it must be defended by the government as being justified by a compelling state interest. See *Memorial Hospital* v. *Maricopa*

County, 415 U.S. 250 (1974); *Roe* v. *Wade,* 410 U.S. 113, 155 (1973); *Lefkowitz* v. *Turley,* 414 U.S. 70, 84-85 (1973); *Shapiro* v. *Thompson,* 394 U.S. 618, 631 (1969); *Sherbert* v. *Verner,* 374 U.S. 398, 407 (1963); *U.S.* v. *Robel,* 389 U.S. 258 (1967); *Griswold* v. *Connecticut,* 381 U.S. 479 (1965); *Aptheker* v. *Secretary of State,* 378 U.S. 500 (1964); *Shelton* v. *Tucker,* 364 U.S. 479 (1960); *Thorpe* v. *Housing Authority,* 386 U.S. 670, 678-679 (1967) (concurring opinion of Mr. Justice Douglas).

The court below did not properly scrutinize the PSRO law to determine whether it was justified by any compelling state interest. Indeed, the government was not even required to respond to the allegations of the complaint—as it should have been required to do in light of the constitutional magnitude of the rights alleged to have been invaded. A physician's right to practice his profession, his patient's right to receive treatment in accordance with his best professional judgment, and the physician-patient relationship itself, all involve constitutionally protected rights.

A physician has a right to practice his profession free of arbitrary government interference. *Doe* v. *Bolton,* 410 U.S. 179 (1973); *Dent* v. *West Virginia,* 129 U.S. 114, 121-22 (1889); *Poe* v. *Menghini,* 339 F.Supp. 986, 995 (D.C. Kan. 1972). *Cf. Meyer* v. *Nebraska,* 262 U.S. 390, 399 (1923). The legal balance between a physician's right to practice his profession and the government's right to regulate his conduct long has been struck upon the principle that the public's interest in health care is best served, not by legislating standards of diagnosis and treatment to which practitioners must adhere, but by limiting access to practice to those persons who, because of their technical skills, will be capable of accurate medical judgments, and who, because of their moral character, will in fact make such judg-

ments solely according to the best interest of their patients. See *Doe* v. *Bolton,* 410 U.S. 179 (1973); *Poe* v. *Menghini,* 339 F.Supp. 986, 995 (D.C. Kan. 1972). A license to practice medicine carries with it presumptions of competence and regularity of motive and conduct that are not lightly overcome by government regulation predicated upon contrary presumptions. *Doe* v. *Bolton,* 410 U.S. 179, 199, and concurring opinion of Mr. Justice Douglas at page 219 (1973). *Cf. United States* v. *Vuitch,* 402 U.S. 62, 70-71 (1971). The legal protection afforded by these presumptions must be considered an intrinsic part of a physician's constitutionally protected right to practice his profession.

The primary purpose of the PSRO law is to control the rapidly rising costs of government health care delivery systems. It represents partial abandonment of attempts to control the costs of health care delivery systems through output controls such as spot reviews, in favor of a system of prior restraint, or input controls, in the form of pre-set norms of practice and screening devices enforced by sanctions. Implicit in this legislative judgment that prior restraints on a physician's medical judgment concerning matters of care, diagnosis and treatment are necessary, is the assumption that, where federally-financed health care is involved, self-regulation based upon moral, ethical and professional considerations no longer is functioning, and cannot be corrected by the usual legal sanctions for unprofessional conduct. Appellant physicians' allegation in the court below that the vague duties imposed under threat of sanction by the PSRO law will have a chilling effect on their exercise of this right states a claim upon which relief could be granted. See *Speiser* v. *Randall,* 357 U.S. 513, 526 (1958). It makes no difference, as the district court seemed to believe (App. B, pp.

11a, 15a), that the threat of the law may be to their economic interests, rather than their personal liberty. See *Nyberg* v. *City of Virginia,* 495 F.2d 1342, 1344 (8th Cir. 1974); *Wulff* v. *Singleton,* 508 F.2d 1211 (8th Cir. 1975); *Abele* v. *Markle,* 452 F.2d 1121, 1125 (2nd Cir. 1971).

It is equally clear that appellants' allegations that the legislation in question impinges upon the physician-patient relationship and the rights of privacy of their patients states a claim of violation of rights guaranteed them by the First, Fifth and Ninth Amendments to the federal Constitution, see *Doe* v. *Bolton,* 410 U.S. 179, 197 and 219 (concurring opinion of Mr. Justice Douglas) (1973). The district court's opinion to the contrary notwithstanding (App. B, p. 16a), these claims were not premature, see *YWCA of Princeton* v. *Kugler,* 342 F.Supp. 1048, 1055 (D.C. N.J. 1972); *Doe* v. *Dunbar,* 320 F.Supp. 1297, 1301 (D.C. Colo. 1970); *Reed* v. *Gardner,* 261 F.Supp. 87, 92 (C.D. Calif. 1966), and appellants had standing to raise them on behalf of their patients, see *Doe* v. *Bolton,* 410 U.S. 179 (1973); *Griswold* v. *Connecticut,* 381 U.S. 479, 481 (1965); *Doe* v. *Scott,* 321 F.Supp. 1385, 1387-88 (N.D. Ill. 1971); *Wulff* v. *Singleton,* 508 F.2d 1211, 1213 (8th Cir. 1975); *Roe* v. *Ingraham,* 364 F.Supp. 536, 540 fn. 6 (S.D.N.Y. 1973); *YWCA of Princeton* v. *Kugler, supra* at 1055; *Doe* v. *Dunbar, supra* at 1301.

4. Even if the court below had not committed any other error, its summary rejection of appellants' allegation that the legislation in question is unconstitutionally vague would require reversal of its decision to dismiss the complaint. Appellants contended that the language of the PSRO law is vague in two respects: it is vague in the description of the duties and obligations it imposes, and

vague in the description of the conduct that a PSRO will consider violative of those duties.

The statute requires that, in ordering, authorizing, directing, or arranging for the provision of health care services for a patient by "any other person", physicians must "exercise their professional responsibility" to the "extent" of their "influence and control" over the patient or such other persons to assure that the patient and such other persons will comply with the requirements of the law. 42 USC §1320c-9(a)(1)(C). The law also imposes an obligation upon physicians, "within reasonable limits of professional discretion", "not to take any action" that would authorize hospitalization of a patient when care could be provided more economically in a different type of facility, unless there is no such facility "in the area" where the patient is located. 42 USC §1320c-9(a)(2).

If the Secretary of H.E.W. finds that a physician has "demonstrated" an "unwillingness", or a "lack of ability" to comply with these obligations, he may be temporarily or permanently barred from treating Social Security beneficiaries on a reimbursable basis—in addition to any other sanction provided by law. In the alternative, the Secretary may exact from the physician the cost of the health care services found to have been wrongfully provided, up to $5,000. 42 USC §1320c-9(b)(1)&(3). Under the law, a PSRO may infer "unwillingness" or "lack of ability" from a physician's failure in a "substantial number" of cases to "substantially" comply with an obligation imposed by the law, or from "gross" and "flagrant" violation of any such obligation in one or more instances. 42 USC §1320c-9(b)(1).

Thus, in treating a patient with an eye to whether a reviewing PSRO might find his conduct in violation of the law, a physician will be required to take into account a

host of general and vague proscriptions to which he is expected to conform not only his conduct, but the conduct of others, as well. He must necessarily guess at what degree of effort to control the conduct of others would be viewed by a PSRO as an acceptable exertion of "influence and control", or what conduct might be viewed by the PSRO as a "demonstration" or "unwillingness" or "lack of ability" to comply with the law, or what a PSRO might consider a "substantial" failure to comply, or a "gross" or "flagrant" violation. If he guesses wrong, he faces economic sanctions, blacklisting, and professional stigmatization.

This statutory language imposes duties and obligations upon physicians in terms so vague "that men of common intelligence must necessarily guess at their meaning and differ as to their application" and, therefore, is inconsistent with appellants' right to due process of law. See *Lanzetta* v. *New Jersey,* 306 U.S. 451, 453 (1939); *Connally* v. *General Construction Co.,* 269 U.S. 385, 391 (1926); *YWCA of Princeton* v. *Kugler,* 342 F.Supp. 1048, 1062 (D.C. N.J. 1972).

The trial court's refusal to entertain appellants' charges of statutory vagueness is patently erroneous in three respects. First, the court did not give any consideration to the allegedly vague statutory language discussed above. It merely addressed its attention to terms in the statute such as "medically necessary", "professionally recognized health care standards", and "proper care", and concluded they were not unconstitutionally vague (App. B, p. 23a). Appellants, however, had not charged that those terms were vague. The court also erroneously believed that ". . . much of plaintiffs' argument appears premature because of the absence of any application of these provisions."

(App. B, p. 23a). That view is directly contrary to this Court's holdings that a statute charged with unconstitutional vagueness is to be reviewed without regard to its particular application, *Lanzetta* v. *New Jersey,* 306 U.S. 451, 453 (1939), or its legislative history, *United States* v. *National Dairy Products Corp.,* 372 U.S. 29, 36 (1963). Finally, and most serious, the court below erred in concluding that the constitutional safeguards against unfairly vague statutory language described by this and other courts in reviewing the constitutionality of criminal statutes, do not also apply to civil statutes such as that in question here. This Court has held to the contrary. See *Giaccio* v. *Pennsylvania,* 382 U.S. 399, 402-403 (1966); *Small Co.* v. *American Sugar Ref. Co.,* 267 U.S. 233, 240-242 (1925).

CONCLUSION

For the reasons stated herein, it is submitted that the District Court failed to recognize and protect the constitutional rights of appellants invaded by the legislation in question, that the questions raised by the lower court's decisions are substantial and of public importance, and should be reviewed by this Court.

Respectfully submitted,

R. R. McMAHAN
135 S. LaSalle Street
Chicago, Illinois 60603
Attorney for Appellants

LORD, BISSELL & BROOK
135 S. LaSalle Street
Chicago, Illinois 60603
Of Counsel

APPENDIX A

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, a not-for-profit corporation for and on behalf of its members; and ROY R. GRINKER, SR., GEORGE E. SHAMBAUGH, JR., and EDWARD A. WOLPERT,

Plaintiffs,

vs.

CASPAR W. WEINBERGER, Secretary of the United States Department of Health, Education and Welfare, an Agency of the Federal Government,

Defendant.

No. 73 C 1653

ORDER

This matter having come before the Court on the Motion of Defendant to dismiss, or in the alternative, for Summary Judgment, and the Court having examined all the briefs and having heard oral argument in the above captioned cause, it is hereby ordered that this cause be dismissed for failure to state a claim upon which relief can be granted.

/s/ Wilbur F. Pell
Circuit Judge
United States Court of Appeals
/s/ Thomas R. McMillen
Judge, United States District Court
/s/ William J. Lynch
Judge, United States District Court

May 8, 1975

APPENDIX B

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, a not-for-profit corporation for and on behalf of its members; and ROY R. GRINKER, SR., GEORGE E. SHAMBAUGH, JR., and EDWARD A. WOLPERT,

Plaintiffs,

vs.

CASPAR W. WEINBERGER, Secretary of the United States Department of Health, Education and Welfare, an Agency of the Federal Government,

Defendant.

No. 73 C 1653

MEMORANDUM OF DECISION

Plaintiffs bring this action seeking to enjoin the Secretary of Health, Education and Welfare from implementing the Federal "Professional Standards Review" Law (42 U.S.C. Section 1320c through Section 1320c-19) and to declare said law unconstitutional on its face on the ground that it violates rights guaranteed the plaintiff physicians and their patients by the First, Fourth, Fifth and Ninth Amendments to the United States Constitution. Jurisdiction is invoked pursuant to Section 1331 of Title 28 of the United States Code, and a three-judge court has been convened in accordance with the provisions of 28 U.S.C. Sections 2282 and 2284. This cause now comes before the Court on defendant's motion for summary judgment.

Since there are no factual issues presented to the Court, only issues of law relating to the facial invalidity of the challenged legislation, defendant has framed his motion as one for summary judgment. However, defendant has also indicated, at the hearing on said motion, that his motion could properly be treated as a motion to dismiss the Complaint for failure to state a claim upon which relief can be granted. (Transcript at p. 4).

In order to more fully comprehend the constitutional objections to the challenged legislation it is first necessary to examine the basic statutory framework of the "Professional Standards Review" Law as set out in Sections 1320c through 1320c-19 of Title 42 of the United States Code. Following this examination the Court will consider the various constitutional attacks on the legislation.

I

The Nature of the "Professional Standards Review" Legislation

With the federal government assuming the position as the largest health insurer in the United States through the enactment of the medicare and medicaid programs (42 U.S.C. Sections 1395-1395pp and 42 U.S.C. Sections 1396-1396i respectively), Congress has become increasingly concerned with the tremendous costs incurred in implementing such programs.

In examining the rising cost of these programs the Senate Committee on Finance noted:

> . . . The Committee on Finance has, for several years, focused its attention on methods of assuring proper utilization of these services. That utilization controls are particularly important was extensively revealed in hearings conducted by the subcommittee on medi-

care and medicaid. Witnesses testified that a significant proportion of the health services provided under medicare and medicaid are probably not medically necessary. In view of the per diem costs of hospital and nursing facility care, and the costs of medical and surgical procedures, the economic impact of this overutilization becomes extremely significant. Aside from the economic impact the committee is most concerned about the effect of overutilization on the health of the aged and the poor. Unnecessary hospitalization and unnecessary surgery are not consistent with proper health care. Sen. R. No. 92-1230, 92d Cong., 2d Sess. 254 (1972).

It was directed at this problem of overutilization that Congress enacted Section 249F of Title II of the 1972 Amendments to the Social Security Act, 42 U.S.C. Sections 1320c-1320c-19, entitled "Professional Standards Review." The Congressional intent behind enactment of this legislation is set forth in Section 1320c of Title 42 of the United States Code which provides that payment for services performed under medicare and medicaid will be made:

(1) only when, and to the extent, medically necessary, as determined in the exercise of reasonable limits of professional discretion; and

(2) in the case of services provided by a hospital or other health care facility on an inpatient basis, only when and for such period as such services cannot, consistent with professionally recognized health care standards, effectively be provided on an outpatient basis or more economically in an inpatient health care facility of a different type, as determined in the exercise of reasonable limits of professional discretion, 42 U.S.C. Sec. 1320c.

In furtherance of this objective Congress has established, under the Act, a number of new organizations and some new limitations of liability.

Under the challenged legislation the Secretary of Health, Education and Welfare shall establish throughout the United States "appropriate areas" with respect to which "Professional Standards Review Organizations" (hereinafter referred to as "PSRO'S") may be designated. Upon designation of an appropriate area, the Secretary must then enter into an agreement with a "qualified organization" which becomes the PSRO for that area. 42 U.S.C. Section 1320c-1(a).

To be qualified under the Act an organization must be a non-profit professional association composed of licensed doctors practicing in the appropriate area, whose membership includes a substantial proportion of all such doctors in the area. The statute sets forth additional requirements for qualification including a finding by the Secretary of Health, Education and Welfare that the organization is one that is willing and able to perform the functions of a PSRO. 42 U.S.C. Section 1320c-1(b)(2).

After designation of a "qualified organization" as a PSRO for an appropriate area, each PSRO must assume

. . . responsibility for the review of the professional activities in such area of physicians and other health care practitioners and institutional and noninstitutional providers of health care services in the provision of health care services and items for which payment may be made (in whole or in part) under this chapter for the purpose of determining whether—

(A) such services and items are or were medically necessary;

(B) the quality of such services meets professionally recognized standards of health care; and

(C) in case such services and items are proposed to be provided in a hospital or other health care facility on an inpatient basis, such services and items could, consistent with the provision of appropriate medical

> care, be effectively provided on an outpatient basis or more economically in an inpatient health care facility of a different type. 42 U.S.C. Section 1320c-4(a)(1).

In order to assure that services provided under medicare and medicaid are medically necessary and of professional quality, the statute requires practitioners and providers of health care services to furnish such evidence as may reasonably be requested by a PSRO. 42 U.S.C. Section 1320c-9 (a)(2).

If the Secretary agrees with the report and recommendation of a PSRO that a particular practitioner or provider of services has either (1) failed, in a substantial number of cases to comply with any of the obligations set forth in the statute or (2) grossly and flagrantly has violated any such obligation in one or more instances and that sanctions are warranted, that practitioners or provider may be excluded from participation in the medicare and medicaid programs. 42 U.S.C. Section 1320c-9(b)(1). The legislation provides for notice and hearing of such determinations. 42 U.S.C. Section 1320c-9(b)(4).

Each PSRO will have the authority to determine whether any elective admission to a hospital or other health care facility, or any other health care service which will consist of extended or costly courses of treatment is medically necessary or could be provided for in a more economical manner. 42 U.S.C. Section 1320c-4(a)(2). If a PSRO determines that such services are not medically necessary or that they could be performed in a more economical manner, no federal funds may be used as payment for such service. 42 U.S.C. Section 1320c-7. However, the Act provides that only a licensed physician can make a final determination as to the professional conduct of any other physician. 42 U.S.C. Section 1320c-4(c).

The legislation also requires a PSRO to give notice of any determination denying a request for approval of health care service or auy determination that a practitioner or provider has violated any obligation imposed by the statute. 42 U.S.C. Section 1320c-10. In determining whether the services rendered are consistent with the criteria set forth in Section 1320c-4(a)(1), PSRO's are required to maintain profiles on each practitioner and provider of health care services. A coding method is employed in order to provide maximum confidentiality and objective evaluation. 42 U.S.C. Section 1320c-4(a)(4).

To aid each PSRO on its evaluation and review process certain professional norms of care, diagnosis and treatment are established which shall include the types and extent of health care services considered within the range of appropriate diagnosis and treatment for a particular illness or condition and the most economical type of health care facility considered medically appropriate. 42 U.S.C. Section 1320c-5(b). In order to coordinate the activities of various PSRO's and to assist the Secretary in evaluating the performance of each PSRO, a number of statewide Professional Standards Review Councils and a National Professional Standards Review Council are to be established by the Secretary. 42 U.S.C. Section 1320c-11(a) and 42 U.S.C. Section 1320c-12(a).

Finally, the challenged legislation provides certain limitations of liability including a section that provides that:

> No doctor of medicine or osteopathy and no provider (including directors, trustees, employees, or officials thereof) of health care services shall be civilly liable to any person under any law of the United States or of any State (or political subdivision thereof) on account of any action taken by him in compliance with

or reliance upon professionally developed norms of care and treatment applied by a Professional Standards Review Organization . . . operating in the area where such doctor of medicine or osteopathy or provider took such action but only if—

(1) he takes such action (in the case of a health care practitioner) in the exercise of his profession as a doctor of medicine or osteopathy (or in the case of a provider of health care services) in the exercise of his functions as a provider of health care services, and

(2) he exercised due care in all professional conduct taken or directed by him and reasonably related to, and resulting from, the actions taken in compliance with or reliance upon such professionally accepted norms of care and treatment. 42 U.S.C. Section 1320c-16(c).

In summary, the Court notes that the "Professional Standards Review" Law is a massive piece of legislation which represents, for the first time, a nationwide program of medical utilization review.

II

Constitutionality of the "Professional Standards Review" Legislation

Given these pertinent statutory sections as background, plaintiffs seek a declaratory judgment that the legislation is unconstitutional on its face and a permanent injunction restraining the defendant from implementing the legislation. Plaintiffs' challenges to the constitutionality of the legislation have their origin in the First, Fourth, Fifth and Ninth Amendments to the United States Constitution. The basic constitutional challenges to the legislation are:

(A) that the legislation unconstitutionally deprives plaintiffs of their right to practice their profession in violation of the Fifth Amendment;

(B) that the legislation unconstitutionally interferes with the physician-patient relationship in violation of the Fifth Amendment;

(C) that the legislation unconstitutionally invades the privacy of the plaintiffs and their patients in violation of the First, Fourth, Fifth and Ninth Amendments;

(D) that the legislation is unconstitutionally vague and uncertain in violation of the Fifth Amendment;

(E) that Congress unconstitutionally exercised its power in imposing limitations of liability under the legislation in violation of the Fifth Amendment;

(F) that the legislation unconstitutionally creates presumptions inconsistent with plaintiffs' licensure in violation of the Fifth Amendment; and

(G) that the legislation unconstitutionally empowers biased private organizations to exercise quasi-judicial authority over plaintiffs in violation of the Fifth Amendment.

Since the Act has yet to be applied, these constitutional challenges are addressed to the constitutionality of the Act on its face. Due to the full panoply of constitutional rights that is alleged to be infringed by numerous provisions of the "Professional Standards Review" legislation and due to the fact that the instant case represents one of the first constitutional challenges to this new legislation, it becomes necessary for the Court to consider each of these contentions separately and in some detail.

A. Plaintiffs' Right to Practice Their Profession

Plaintiffs argue that the challenged legislation violates their constitutional rights as guaranteed by the Fifth Amendment in that it is arbitrary and overbroad and interferes with the plaintiffs' right to practice their profession.

Similar arguments were raised in the case of *Rasulis* v. *Weinberger,* 502 F. 2d 1006 (7th Cir. 1974). The statutory regulation under attack in *Rasulis* established professional standards which physicial therapists must meet in order to qualify for reimbursement under the Medicare Program. 20 C.F.R. Sec. 405.1101(q).

In rejecting plaintiffs' argument that the regulation was arbitrary and violative of the Due Process Clause of the Fifth Amendment, the Court of Appeals noted:

> The Due Process Clause prohibits only those classifications within a Federal social welfare program that are patently arbitrary and totally lacking in rational justification. *Fleming* v. *Nestor,* 363 U.S. 603, 611 (1960). Accord, *Gruenwald* v. *Gardner,* 390 F. 2d 591, 592 (2nd Cir. 1968), *cert. denied,* 393 U.S. 982 (1968); *Price* v. *Flemming,* 280 F. 2d 956 (3rd Cir. 1960), *cert. denied,* 365 U.S. 817 (1961). And ". . . regulation which is reasonable in relation to its subject and is adopted in the interests of the community is due process." *West Coast Hotel Co.* v. *Parrish,* 300 U.S. 379, 391 (1937). See generally *Dandridge* v. *Williams,* 397 U.S. 471, 485 (1970); *McGowan* v. *Maryland,* 366 U.S. 420, 425-26 (1961); *Williamson* v. *Lee Optical of Oklahoma,* 348 U.S. 483, 489 (1955). 502 F. 2d at 1009.

Thus, the Court concluded:

> The challenged legislation does not stray outside the boundaries of permissible regulation. It merely provides standards for the dispensation of Federal funds. The economic incentive of participation in the Medicare Program does not constitute coercion or control. See Cardozo J. for the Court in *Steward Machine Co.* v. *Davis,* 301 U.S. 548, 589-90 (1937). 502 F. 2d at 1010.

Although the "Professional Standards Review" legislation represents a more comprehensive regulatory scheme than that encountered in *Rasulis,* the constitutional principles to be applied are the same in each. In order to avoid overutilization of health care services and to achieve more effective control over the costs of those services, Congress has enacted the "Professional Standards Review" legislation. The legislation does set forth certain professional standards which must be met in furtherance of this statutory purpose. The statute, however, does not bar physicians from practicing their profession but only "provides standards for the dispensation of Federal funds." Considering the purpose behind this statutory scheme and the requirements set forth in the statute to achieve this purpose, this Court finds that the challenged legislation is not so "patently arbitrary and totally lacking in rational justification" as to be violative of the Due Process Clause of the Fifth Amendment.

In support of their argument that the challenged legislation is arbitrary in violation of the Fifth Amendment, the defendants have mainly relied on three lines of cases: (1) where the legislation was attacked on the ground that it established an arbitrary or invidious discrimination; (2) where legislation was held to have lacked critical elements of procedural due process; and (3) where certain legislation was found to bear no reasonable relationship to any legitimate governmental end.

Plaintiffs have presented a number of cases involving legislation challenged as establishing arbitrary or invidious discrimination. *Memorial Hospital* v. *Maricopa County,* 94 S. Ct. 1076 (1974); *United States Department of Agriculture* v. *Moreno,* 413 U.S. 528 (1973); and *Shapiro* v. *Thompson,* 394 U.S. 618 (1969). However, the instant complaint lacks any specifications of how the "Professional Standards Review" Law creates any arbitrary or invidious discrimination.

In addition, these cases offered by plaintiffs can easily be distinguished from the case at bar. The case of *Memorial Hospital* v. *Maricopa County, supra,* struck down a one-year state residency requirement for county financed medical care on the ground that it created an invidious distinction between classes of citizens. In *United States Department of Agriculture* v. *Moreno, supra,* the Court struck down a statute limiting eligibility for food stamps to households consisting only of related individuals because such a limitation constituted a classification "wholly without any rational basis." 413 U.S. at 538.

Similarly, in *Shapiro* v. *Thompson, supra,* the Supreme Court invalidated a one-year residency requirement for becoming eligible for Medicare on the ground that this legislative scheme established invidious discrimination. Unlike the statutory schemes invalidated as creating an arbitrary or invidious discrimination in *Maricopa, Moreno* and *Shapiro,* the challenged legislation in the instant suit does not establish any arbitrary or invidious discrimination in violation of the Fifth Amendment. Thus, the Court finds that these cases are not supportive of plaintiffs' position that the "Professional Standards Review" Law is arbitrary in violation of the Fifth Amendment.

Plaintiffs have further argued that this legislation lacks critical elements of procedural due process. Such an argument is not well-founded. Section 1320c-9(b)(4) of Title 42 of the United States Code provides that no physician can be barred from participation in the Medicare or Medicaid programs without notice and a hearing. Further, the legislation allows a hearing and review by the Secretary of all PSRO determinations denying payment for services where the amount in controversy is $100.00 or more; and if that amount is $1,000.00 or more, the aggrieved party is

entitled to judicial review of an adverse determination by the Secretary. 42 U.S.C. Sec. 1320c-8. Finally, the challenged legislation provides that a PSRO must give notice to any practitioner or provider of any determination (1) denying any request for approval of health care service or (2) that such practitioner or provider has violated any obligation imposed upon him by the legislation. 42 U.S.C. Sec. 1320c-10.

These statutory provisions satisfy the demands of procedural due process by apprising the practitioner or provider of any adverse determination and by affording him an opportunity to be heard either by the Secretary or through the avenue of judicial review. Such safeguards are consonant with the concept of procedural due process as embodied in the Fifth Amendment.

Finally, plaintiffs argue that the legislation is arbitrary because it bears no reasonable relationship to any end within the competency of government. As the plaintiffs themselves have noted, "the primary purpose of the Act is to control the rapidly rising costs of governmental health care delivery systems." (Plaintiffs' Memorandum in Opposition at page 23). Such a statutory purpose can hardly be considered to be one outside the competency of the federal government, particularly in light of the already extensive government regulation in the health care field.

Plaintiffs have also attacked the Act on the ground that it is unconstitutionally overbroad citing the case of *City of Carmel-by-the-Sea* v. *Young,* 2 Cal. 2d 259, 466 P.2d 225, 85 Cal. Rptr. 1 (1970). In *City of Carmel* a state statute requiring all public officers and candidates to disclose not only their own financial investments but also those of their families was struck down as being overbroad.

However, the United States Supreme Court in *Dandridge* v. *Williams,* 397 U.S. 471 (1970), has indicated that the overbreadth doctrine has little application to social welfare legislation.

> For this Court to approve the invalidation of state economic or social regulation as "overreaching" would be far too reminiscent of an era when the Court thought the Fourteenth Amendment gave it power to strike down state laws "because they may be unwise, improvident, or out of harmony with a particular school of thought." *Williamson* v. *Lee Optical Co.,* 348 U.S. 483, 488. That era long ago passed into history, *Ferguson* v. *Skrupa,* 372 U.S. 726. *Dandridge* v. *Williams,* 397 U.S. at 484-85.

Accordingly, the Court finds plaintiffs' argument that the instant legislation is unconstitutionally overbroad to be wholly without merit.

Finally, plaintiffs argue that the challenged legislation violates the Fifth Amendment in that it unconstitutionally interferes with their right to practice. In support of this argument plaintiffs place heavy reliance on a series of decisions striking down various criminal abortion statutes. *Doe* v. *Bolton,* 410 U.S. 179 (1973); *Roe* v. *Wade,* 410 U.S. 113 (1973); *Poe* v. *Menghini,* 339 F. Supp. 986 (D. Kan. 1972) (three judge court).

In *Doe* v. *Bolton, supra,* and *Roe* v. *Wade, supra,* the Supreme Court struck down the Georgia and Texas criminal abortion statutes respectively. In *Doe* v. *Bolton, Roe* v. *Wade* and *Poe* v. *Menghini,* the challenged statutes provided criminal penalties for performing abortions except under specified circumstances.

The "Professional Standards Review" Law does not prohibit a physician from performing any surgical operations

he deems necessary in the exercise of his professional skill and judgment. It merely provides that if a practitioner wishes to be compensated for his services by the federal government, he is required to comply with certain guidelines and procedures enumerated in the statute.

These statutory requirements do not act in the same mandatory fashion upon the plaintiffs as did the criminal abortion statutes invalidated in *Doe* v. *Bolton,* and *Roe* v. *Wade.* Rather the legislation sets forth certain review procedures to be complied with for any practitioner wishing to participate in the program and to be paid by the federal government.

Underlying the constitutionality of the challenged legislation is the basic premise that each individual physician and practitioner has the ability to choose whether or not to participate in the program. It is true that there will exist economic incentive or inducement to participate in the program. However, such inducement is not tantamount to coercion or duress.

In *Steward Machine Co.* v. *Davis,* 301 U.S. 548 (1937), the constitutionality of a social security tax on employers was attacked on the ground that it constituted coercion on states to enact welfare programs by allowing a credit against the tax for taxes paid to state welfare plans. In rejecting the contention that the legislation unconstitutionally coerced states into enacting welfare programs, Justice Cardozo, speaking for the Court stated:

> But to hold that motive or temptation is equivalent to coercion is to plunge the law in endless difficulties. The outcome of such a doctrine is the acceptance of a philosophical determination by which choice becomes impossible. Till now the law has been guided by a robust common sense which assumes the freedom of will

as a working hypothesis in the solution of its problems. [301 U.S. at 589-90]

In applying the "common sense" approach of Justice Cardozo to the question of whether the instant legislation is coercive in nature, the Court finds that the statute does not act upon the plaintiffs in such a mandatory fashion as to amount to an unconstitutional interference with plaintiffs' right to practice.

B. Interference with the Physician-Patient Relationship

Plaintiffs argue that the challenged legislation unconstitutionally interferes with the doctor-patient relationship. Specifically, plaintiffs allege that the system of norms of care, diagnosis and treatment to be established under the statutory scheme, "will have a chilling effect on the case-by-case practice of medicine and innovative progress in medical practice, to the ultimate detriment of plaintiffs and their patients."

Initially the Court notes that plaintiffs' argument appears premature in that the particular norms under attack have yet to be established. The argument is essentially based on the premise that such norms of diagnosis, treatment and care are inherently incapable of reduction to specific language. (Plaintiffs' Memorandum in Opposition at page 21).

The Court is cognizant of the difficulties encountered in drafting norms with sufficient specificity to afford meaningful notice to the practitioner and with adequate flexibility to reach a multitude of individual medical cases. However, the task is not an impossible one. Although the challenged legislation establishes, for the first time, a unified national program of medical utilization review, norms have been

employed in private medical utilization review programs for a number of years. See *R. B. Schumer, Hospital Utilization Review and Medicare: A Survey* at pages 8-9. (Government Printing Office, Washington, D.C. 1973).

The statute specifically provides that the norms must include:

> . . . the type and extent of the health care service which, taking into account differing, but acceptable, modes of treatment and methods of organizing and delivering care are considered within the range of appropriate diagnosis and treatment of such illness or health condition, consistent with professionally recognized and accepted patterns of care . . . 42 U.S.C. Sec. 1320c-5 (b)(1).

Further, the purpose behind the implementation of these norms was clearly set forth in the legislative history of the statute:

> Neither should the use of norms as check-points nor any other activity of the PSRO be used to stifle innovative medical practice or procedures. The intent is not conformism in medical practice—the objective is reasonableness. Sen. R. No. 92-1230 at 263.

Given the legislative standard of reasonableness and the statutory flexibility to take into account various methods of treatment, the Court finds no merit to plaintiffs' argument that the system of norms to be established under the statutory scheme will unconstitutionally interfere with the physician-patient relationship.

C. The Right of Privacy of Plaintiffs and Their Patients

Plaintiffs argue that the statutory sections requiring plaintiffs to furnish information concerning their patients

violate the constitutional right of privacy of plaintiffs and their patients as guaranteed by the First, Fourth, Fifth and Ninth Amendments.

The purpose of the information sought from plaintiffs is to enable the Professional Standards Review Organization to assemble patient profiles upon which they can determine whether the services performed under the Medicare and Medicaid Programs were medically necessary and done in an economical manner. The legislation also provides that reporting procedures should utilize to the greatest extent possible "methods of coding which will provide maximum confidentiality as to patient identity and assure objective evaluation consistent with the purposes of this part." 42 U.S.C., Section 1320c-4.

Further, the statute provides in pertinent part that:

> (a) Any data or information acquired by any Professional Standards Review Organization, in the exercise of its duties and functions, shall be held in confidence and shall not be disclosed to any person except (1) to the extent that may be necessary to carry out the purposes of this part or (2) in such cases and under such circumstances as the Secretary shall by regulations provide to assure adequate protection of the rights and interests of patients, health care practitioners, or providers of health care.
>
> (b) It shall be unlawful for any person to disclose any such information other than for such purposes, and any person violating the provisions of this section shall, upon conviction, be fined not more than $1,000 and imprisoned for not more than six months, or both, together with the costs of prosecution. 42 U.S.C., Section 1320c-15.

These statutory provisions make it clear that the maximum confidentiality is to be maintained concerning the information furnished by the physicians to the Professional Standards Review Organizations.

In *California Bankers Association* v. *Shultz*, 416 U.S. 21 (1974), the Supreme Court considered whether various provisions of the Bank Secrecy Act of 1970 and regulations promulgated thereunder amounted to an unconstitutional invasion of privacy. Under the authority of the Act, the Secretary of the Treasury promulgated regulations requiring banks to report domestic currency transactions of $10,000 or more. In upholding the constitutionality of the regulation, the Court stated:

> The regulations do not impose unreasonable reporting requirements on the banks. The regulations require the reporting of information with respect to abnormally large transactions in currency, much of which information the bank as a party to the transaction already possesses or would acquire in its own interest. To the extent that the regulations in connection with such transactions require the bank to obtain information from a customer simply because the Government wants it, the information is sufficiently described and limited in nature, and sufficiently related to a tenable congressional determination as to improper use of transactions of that type in interstate commerce, so as to withstand the Fourth Amendment challenge made by the bank plaintiffs. "(T)he inquiry is within the authority of the agency, the demand is not too indefinite and the information sought is reasonably relevant. 'The gist of the protection is in the requirement, expressed in terms, that the disclosure sought shall not be unreasonable.'" *United States* v. *Morton Salt Co., supra,* at 652-653; see *Oklahoma Press Publishing Co.* v. *Walling,* 327 U.S. 186, 208 (1946).

The challenged legislation in the instant suit seeks information for a legitimate governmental purpose. The man-

ner in which the information is gathered and maintained is reasonable in light of the above-quoted statutory provisions that are designed to assure proper confidentiality. The Court finds that these provisions do not infringe on the constitutionally protected right of privacy of plaintiffs.

In support of their argument that the legislation violates their right of privacy, plaintiffs place heavy emphasis on the case of *Roe* v. *Ingraham,* 480 F.2d 102 (2d Cir. 1973). In *Roe* the Second Circuit Court of Appeals considered the constitutionality of a New York law which required that certain drugs be prescribed only on a state prescription form, two copies of which had to be filed with the State Department of Health. In reversing the District Court's dismissal of the suit, the Court of Appeals significantly noted:

> If it were clear that the State had taken or proposed to take effective steps, by regulation or otherwise, to limit access to the patients' names on the prescription forms as rigidly as is consistent with accomplishment of the asserted statutory purpose, the grounds for constitutional attack might disappear. 480 F.2d at 109.

The case of *Roe* v. *Ingraham, supra,* can be distinguished from this suit. Unlike the statute under constitutional attack here, the "Professional Standards Review" Law does limit access to the information under penalty of criminal sanctions. After reviewing a number of cases dealing with the right of privacy, the Supreme Court in *Roe* v. *Wade, supra,* noted:

> Although the results are divided, most of these courts have agreed that the right of privacy, however based, is broad enough to cover the abortion decision; that the right, nonetheless, is not absolute and is subject to some limitations; and that at some point the state interests as to protection of health, medical standards,

> and prenatal life, become dominant. We agree with this approach. [410 U.S. at 155]

The "Professional Standards Review" legislation contains provisions that properly balance the plaintiffs' right of privacy with the Government's interest in maintaining proper health care in an economical manner.

Finally, in regard to plaintiffs' contentions concerning their right to privacy, the Court notes that plaintiffs have argued that the legislation violates the constitutional right of privacy of their patients. It is not at all clear that plaintiffs have the requisite standing in this case to assert the constitutional rights of their patients.

In *California Bankers Association* v. *Schultz,* 416 U.S. 21 (1974), the Supreme Court considered whether a private bank had standing to assert the right of their depositors. There the Court noted:

> It is true that in a limited class of cases this Court has permitted a party who suffered injury as a result of the operation of a law to assert his right even though the sanction of the law was borne by another, *Pierce* v. *Society of Sisters,* 268 U.S. 510 (1925), and conversely, the Court has allowed a party upon whom the sanction falls to rely on the wrong done to a third party in obtaining relief, *Barrows* v. *Jackson,* 346 U.S. 249 (1953); *Eisenstadt* v. *Baird,* 405 U.S. 438 (1972). Whether the bank might in other circumstances rely on an injury to its depositors or whether, instead, this case is governed by the general rule that one has standing only to vindicate his own rights, e.g., *Moose Lodge* v. *Irvis,* 407 U.S. 163, 166 (1972), need not now be decided, since, in any event, the claim is premature. 416 U.S. at 51.

Under the circumstances of this case, the claim of the plaintiffs on behalf of their patients is similarly prema-

ture. This suit attacks the constitutionality of the legislation on its face, and thus far there is no showing that a real and immediate injury or threat of injury exists to particular patients of these plaintiffs.

As the Supreme Court stated in *California Bankers Association* v. *Schultz, supra*:

> Plaintiffs in the federal courts "must allege some threatened or actual injury resulting from the putatively illegal action before a federal court may assume jurisdiction." *Linda R.S.* v. *Richard D.*, 410 U.S. 614, 617 (1973). There must be a "personal stake in the outcome" such as to "assure that concrete adverseness which sharpens the presentation of issues upon which the court so largely depends for illumination of difficult constitutional questions." *Baker* v. *Carr*, 369 U.S. 186, 204 (1962) . . . Abstract injury is not enough. It must be alleged that the plaintiff "has sustained or is immediately in danger of sustaining some direct injury as a result of the challenged statute or official conduct. *Massachusetts* v. *Mellon*, 262 U.S. 447, 488 (1923). The injury or threat of injury must be both "real and immediate," not "conjectural" or "hypothetical." *Golden* v. *Zwickler*, 394 U.S. 103, 109-110 (1969); *Maryland Casualty Co.* v. *Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941); *United Public Workers* v. *Mitchell*, 330 U.S. 75, 89-91 (1947); *O'Shea* v. *Littleton*, 414 U.S. 488, 493-494 (1974). 416 U.S. 21, 68-69.

In summary, the Court finds that the reporting procedures in the challenged legislation do not unconstitutionally interfere with plaintiffs' right to privacy. These procedures are reasonable in scope in that they contain provisions designed to assure confidentiality. Like the reporting procedure upheld in *California Bankers*, through these provisions "Congress is simply imposing a condition on the spending of public funds." 416 U.S. at 50.

D. Vagueness

Plaintiffs have argued that numerous words and phrases contained in this lengthy statute are so vague and uncertain "that plaintiffs must necessarily guess at their meaning" and that this lack of specificity is contrary to the requirements of the Fifth Amendment. In support of this position plaintiffs have cited numerous decisions involving criminal statutes invalidated under the vagueness doctrine.

Initially, the Court notes that much of plaintiffs' argument appears premature because of the absence of any application of these provisions. Nevertheless, the Court will consider plaintiffs' constitutional objections as they relate to the vagueness and uncertainty of the legislation on its face.

The test in determining whether or not a statute is unconstitutionally vague is whether men or common intelligence must necessarily guess at its meaning. Due to the particular application of this statute to physicians and other practitioners, the Court must also consider whether members of the medical profession must necessarily guess at the meaning of phrases set forth in the statute, such as "medically necessary," "professionally recognized health care standards," and "proper care."

Although the Court recognizes that these phrases are not highly specific, the Court believes that the language of the challenged legislation is not impermissibly vague or uncertain. As the Supreme Court stated in *United States* v. *Petrillo*, 326 U.S. 1, 7-8 (1947):

> . . . the Constitution does not require impossible standards. The language here challenged conveys sufficiently definite warning as to the proscribed conduct when measured by common understanding and practices. The Constitution requires no more.

Plaintiffs' reliance on numerous decisions invalidating various criminal statutes on the grounds of vagueness is misplaced. The present statutory scheme does not impose criminal sanctions. Nor does it provide for severance from the medical profession for non-compliance. See e.g., *Hewitt* v. *Board of Medical Examiners,* 148 Cal. 590, 84 P. 39 (1906). Rather the instant legislation only sets forth conditions for being compensated by federal funds under the Medicare and Medicaid Programs. As was stated earlier, Congress faced a difficult task in drafting this statute with sufficient specificity to give the physicians, practitioners and providers of health care service adequate notice of the new requirements of the law and at the same time to maintain enough flexibility to cover a variety of medical cases. In accomplishing this task Congress did not stray beyond the permissible standards of the Constitution.

E. Constitutionality of the Limitations of Liability

The challenged legislation establishes certain limitations as provided, *supra,* in Section 1320c-16(c) of Title 42 of the United States Code. Plaintiffs contend that Congress lacks authority to grant legal immunity against common law tort liability; and if the immunity provisions of the challenged legislation are enforceable, the legislation imposes duties and obligations on plaintiffs which may unconstitutionally expose them to civil liability.

The Court does not now reach the merits of these claims because the plaintiffs lack the requisite standing to challenge the constitutionality of these limitations of liability. The proper party to raise such objections would be the beneficiaries or recipients under the Medicare and Medicaid Programs.

Further, plaintiffs' allegation that they "will be exposed to a serious risk of civil liability as a result of complying with the law" does not amount to a real and immediate threat of injury which would confer standing on these plaintiffs at this time.

The norms which are to be established and which the plaintiffs must comply with are, by definition, typical medical practices within the region where the physician practices. If a physician does not follow such typical procedures, he might be held liable for malpractice under state common law. The risk of civil liability arises from common law standards of negligence, not from the statute.

Thus, the possibility of exposure to civil liability sometime *in futuro* as a result of complying with these statutory norms does not amount to that type of real and immediate threat of injury which is necessary to sharpen the issues and place them in proper posture for adjudication. See *Baker* v. *Carr,* 369 U.S. 186, 204 (1962). There being no actual case or controversy at this time, the Court does not now reach the issue of the constitutionality of the limitations of liability established by the "Professional Standards Review" Law.

F. Presumptions Inconsistent with Plaintiffs' Licensure

Plaintiffs contend that the medical license carries certain presumptions of competence, good moral character, and regularity of motive and conduct, and that inconsistent presumptions are created by the statutory requirement that plaintiffs must provide evidence of their performance of services. In support of this position plaintiffs rely on language in the decision of *Doe* v. *Bolton, supra,* which

struck down the two doctor concurrence requirement in the Georgia criminal abortion statute because such a requirement had "no rational connection with a patient's needs and unduly infringes on the physician's right to practice." 410 U.S. at 199.

The case of *Doe* v. *Bolton* is inapposite, however. It involved a criminal abortion statute which barred performance of a surgical operation. The section challenged by plaintiffs here merely provides that practitioners must furnish evidence of their services in order to be compensated.

To read *Doe* v. *Bolton* as holding invalid any regulation of physicians other than by licensure is unfounded as noted by the Second Circuit Court of Appeals in *Roe* v. *Ingraham, supra*:

> Also, we do not read the portion of *Doe* v. *Bolton, supra,* 410 U.S. at 198, 93 S.Ct. 739, striking down Georgia's "two doctor concurrence" requirement as meaning that a state is wholly without power to regulate the practice of medicine or the activities of physicians except by professional censure, deprivation of licenses, or enforcement of the criminal law. 480 F. 2d at 108.

Accordingly, plaintiffs' contention that the statute creates presumptions inconsistent with plaintiffs' licensure in violation of the Fifth Amendment is without merit.

G. Delegation of Authority to Private Organizations

Plaintiffs contend:

> Said law, and in particular Section 1152 of said law (42 U.S.C. Section 1320c-1), empowers private organizations that are inherently biased against plaintiffs by their contractual relationship with defendant and their economic self-interest, to exercise quasi-judicial au-

> thority over plaintiffs. . . . [Complaint, Part IV, Paragraph 11.]

In support of this argument plaintiffs rely on the case of *Tumey* v. *Ohio,* 273 U.S. 510 (1927), where the Supreme Court struck down a state statute which provided that certain crimes be tried before the Mayor of a town who received remuneration only if the defendant was found guilty. Plaintiffs argue that like the Mayor in *Tumey,* the PSRO's in the instant case will have a financial interest in retaining their contract. This argument is ill-founded for several reasons.

First, by statute, the PSRO's must be non-profit organizations, 42 U.S.C., Section 1320c-1(c)(1). Second, these PSRO's will be reimbursed by the Secretary for their expenses, including the salaries of personnel performing review functions. 42 U.S.C. Section 1320c-4(f)(2). Accordingly, the amount of salary is not related to performance as was the case in *Tumey* v. *Ohio, supra.* Membership in a PSRO is open to every physician in the PSRO's area, 42 U.S.C. Section 1320c-1(b)(1)(A); and all review of medical decisions must be made by physicians, 42 U.S.C. Section 1320c-4(c). Thus, plaintiffs' allegation that these private organizations will be biased is totally without merit.

Finally, it has been held permissible for agencies of the federal government to contract with private organizations in order to have such organizations perform governmental functions as long as the particular administrative scheme provides for a hearing on the determinations made by those private organizations. See *State of Texas* v. *National Bank of Commerce of San Antonio,* 290 F.2d 229 (5th Cir.), *Cert. denied,* 368 U.S. 832 (1961), and *Coral Gables Convalescent Home, Inc.* v. *Richardson,* 340 F. Supp. 646 (S.D. Fla. 1972).

III.

Valid Exercise of Congressional Power

Plaintiffs' final argument, buttressed by a lengthy amicus curiae brief filed by the Association of Councils of Medical Staffs of Private Hospitals, Inc., is a broad attack upon the legislation as an inefficient and unnecessary interference with their right to practice medicine. This Court has already held, *supra,* that the "Professional Standards Review" legislation does not unconstitutionally interfere with plaintiffs' right to practice their profession in violation of the Fifth Amendment.

Congress has enacted this legislation as a vehicle to better control expenditures of the federal government in connection with the Medicare and Medicaid Programs. In view of the already extensive presence of the federal government in the health care sphere, it can hardly be said that a statutory scheme designed to achieve better cost control in the field of health care is outside the competency of the federal government.

The means that Congress has chosen to attain these economic goals are not arbitrary and totally lacking in rationality. Underlying the constitutionality of the legislation is the fact that the program is a voluntary one in which a physician may freely choose whether or not to participate. However, should a physician choose to participate, he must then comply with these new requirements in order to be compensated for his services.

This legislation represents the first medical utilization review program that is national in scope. In attempting to avoid overutilization and to achieve better cost control in the health care field, the "Professional Standards Review"

Law comes in close proximity to the rights of those physicians and other providers of health care services in the Medicare and Medicaid Programs. Yet there must be a balancing between those interests and the government interest in providing and maintaining medical care to those most in need of it.

The "Professional Standards Review" legislation properly preserves that balancing of interests. In upholding the constitutionality of the legislation on its face, this Court does not reach the validity of the statute as it will be applied. Nor does this Court pass upon the wisdom of this particular piece of legislation. Whether the implementation and application of this statute may result in an unwieldy bureaucracy of monstrous proportions is a policy question for the consideration of the legislative rather than the judicial branch of the government.

As the United States Supreme Court noted in upholding the constitutionality of a provision of the Social Security Act in *Richardson* v. *Belcher*, 404 U.S. 78 (1971):

> We have no occasion, within our limited function under the Constitution, to consider whether the legitimate purposes of Congress might have been better served . . . or to judge for ourselves whether the apprehensions of Congress were justified by the facts. If the goals sought are legitimate, and the classification adopted is rationally related to the achievement of those goals, then the action of Congress is not so arbitrary as to violate the Due Process Clause of the Fifth Amendment. *Id.* at 84.

IV.

Conclusion

For the foregoing reasons, defendant's motion to dismiss for failure to state a claim upon which relief can be granted, or, in the alternative, for summary judgment, is hereby granted.

The Cause is dismissed.

ENTER:

/s/ Wilbur F. Pell
Circuit Judge
United States Court of Appeals
/s/ Thomas R. McMillen
Judge, United States District Court
/s/ William J. Lynch
Judge, United States District Court

Dated: May 8, 1975

APPENDIX C

IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

ASSOCIATION OF AMERICAN PHYSICIANS AND SURGEONS, a not-for-profit corporation for and on behalf of its members; and ROY R. GRINKER, SR., GEORGE E. SHAMBAUGH, JR., and EDWARD A. WOLPERT,
Plaintiffs,
vs.
CASPAR W. WEINBERGER, Secretary of the United States Department of Health, Education and Welfare, an Agency of the Federal Government,
Defendant.
} No. 73 C 1653

NOTICE OF APPEAL TO THE
SUPREME COURT OF THE UNITED STATES

Notice is hereby given that the Association of American Physicians and Surgeons, et al., plaintiffs herein, hereby appeal to the Supreme Court of the United States from the judgment order entered in this action on May 8, 1975.

This appeal is taken pursuant to 28 U.S.C. §1253.

R. R. McMahan
LORD, BISSELL & BROOK
135 South LaSalle Street
Chicago, Illinois 60603
By /s/ R. R. McMahan
Attorneys for Plaintiffs

CERTIFICATE OF SERVICE

I hereby certify that on this 7th day of July, 1975, copies of the foregoing Notice of Appeal to the Supreme Court of the United States were mailed, postage prepaid, to:

The Solicitor General
United States Department of Justice
Washington, D.C. 20530

Hon. Caspar W. Weinberger
Secretary of the United States
Department of Health, Education
and Welfare
Washington, D.C. 20201

Hon. Samuel K. Skinner
Acting United States Attorney
219 South Dearborn
Chicago, Illinois 60604

I further certify that all parties required to be served have been served.

/s/ R. R. McMahan

SUBSCRIBED and SWORN to before
me this ..... day of July, 1975.

.....
Notary Public

APPENDIX D

Statutes Involved

[Section 249F(b) of the Social Security Amendments of 1972, October 30, 1972, Public Law 92-603, Title II, §249F(b), 86 Stat. 1429; 42 USC §§1320c, *et seq.*]

42 USC 1320c.

In order to promote the effective, efficient and economical delivery of health care services of proper quality for which payment may be made (in whole or in part) under this chapter and in recognition of the interests of patients, the public, practitioners, and providers in improved health care services, it is the purpose of this part to assure, through the application of suitable procedures of professional standards review, that the services for which payment may be made under this chapter will conform to appropriate professional standards for the provision of health care and that payment for such services will be made—

(1) only when, and to the extent, medically necessary, as determined in the exercise of reasonable limits of professional discretion; and

(2) in the case of services provided by a hospital or other health care facility on an inpatient basis, only when and for such period as such services cannot, consistent with professionally recognized health care standards, effectively be provided on an outpatient basis or more economically in an inpatient health care facility of a different type, as determined in the exercise of reasonable limits of professional discretion.

42 USC 1320c-1.

(a) The Secretary shall (1) not later than January 1, 1974, establish throughout the United States appropriate areas with respect to which Professional Standards Review Organizations may be designated, and (2) at the earliest practicable date after designation of an area enter into an agreement with a qualified organization whereby such an organization shall be conditionally designated as the Professional Standards Review Organization for such area. If, on the basis of its performance during such period of conditional designation, the Secretary determines that such organization is capable of fulfilling, in a satisfactory manner, the obligations and requirements for a Professional Standards Review Organization under this part, he shall enter into an agreement with such organization designating it as the Professional Standards Review Organization for such area.

• • •

42 USC 1320c-4.

(a)(1) Notwithstanding any other provision of law, but consistent with the provisions of this part, it shall (subject to the provisions of subsection (g) of this section) be the duty and function of each Professional Standards Review Organization for any area to assume, at the earliest date practicable, responsibility for the review of the professional activities in such area of physicians and other health care practitioners and institutional and noninstitutional providers of health care services in the provision of health care services and items for which payment may be made (in whole or in part) under this chapter for the purpose of determining whether—

(A) such services and items are or were medically necessary;

(B) the quality of such services meets professionally recognized standards of health care; and

(C) in case such services and items are proposed to be provided in a hospital or other health care facility on an inpatient basis, such services and items could, consistent with the provision of appropriate medical care, be effectively provided on an outpatient basis or more economically in an inpatient health care facility of a different type.

(2) Each Professional Standards Review Organization shall have the authority to determine, in advance, in the case of—

(A) any elective admission to a hospital, or other health care facility, or

(B) any other health care service which will consist of extended or costly courses of treatment,

whether such service, if provided, or if provided by a particular health care practitioner or by a particular hospital or other health care facility, organization, or agency, would meet the criteria specified in clauses (A) and (C) of paragraph (1).

(3) Each Professional Standards Review Organization shall, in accordance with regulations of the Secretary, determine and publish from time to time, the types and kinds of cases (whether by type of health care or diagnosis involved, or whether in terms of other relevant criteria relating to the provision of health care services) with respect to which such organization will, in order most effectively to carry out the purposes of this part, exercise the authority conferred upon it under paragraph (2).

(4) Each Professional Standards Review Organization shall be responsible for the arranging for the maintenance of and the regular review of profiles of care and services received and provided with respect to patients, utilizing to the greatest extent practicable in such patient profiles, methods of coding which will provide maximum confidentiality as to patient identity and assure objective evaluation consistent with the purposes of this part. Profiles shall also be regularly reviewed on an ongoing basis with respect to each health care practitioner and provider to determine

whether the care and services ordered or rendered are consistent with the criteria specified in clauses (A), (B), and (C) of paragraph (1).

• • •

(b) To the extent necessary or appropriate for the proper performance of its duties and functions, the Professional Standards Review Organization serving any area is authorized in accordance with regulations prescribed by the Secretary to—

(1) make arrangements to utilize the services of persons who are practitioners of or specialists in the various areas of medicine (including dentistry), or other types of health care, which persons shall, to the maximum extent practicable, be individuals engaged in the practice of their profession within the area served by such organization;

(2) undertake such professional inquiry either before or after, or both before and after, the provision of services with respect to which such organization has a responsibility for review under subsection (a) (1) of this section;

(3) examine the pertinent records of any practitioner or provider of health care services providing services with respect to which such organization has a responsibility for review under subsection (a) (1) of this section; and

(4) inspect the facilities in which care is rendered or services provided (which are located in such area) of any practitioner or provider.

• • •

42 USC 1320c-5.

(a) Each Professional Standards Review Organization shall apply professionally developed norms of care, diagnosis, and treatment based upon typical patterns of practice in its regions (including typical length-of-stay for institutional care by age and diagnosis) as principal points of evaluation and review. The National Professional

Standards Review Council and the Secretary shall provide such technical assistance to the organization as will be helpful in utilizing and applying such norms of care, diagnosis, and treatment. Where the actual norms of care, diagnosis, and treatment in a Professional Standards Review Organization area are significantly different from professionally developed regional norms of care, diagnosis, and treatment approved for comparable conditions, the Professional Standards Review Organization concerned shall be so informed, and in the event that appropriate consultation and discussion indicate reasonable basis for usage of other norms in the area concerned, the Professional Standards Review Organization may apply such norms in such area as are approved by the National Professional Standards Review Council.

(b) Such norms with respect to treatment for particular illnesses or health conditions shall include (in accordance with regulations of the Secretary)—

(1) the types and extent of the health care services which, taking into account differing, but acceptable, modes of treatment and methods of organizing and delivering care are considered within the range of appropriate diagnosis and treatment of such illness or health condition, consistent with professionally recognized and accepted patterns of care;

(2) the type of health care facility which is considered consistent with such standards, to be the type in which health care services which are medically appropriate for such illness or condition can most economically be provided.

(c)(1) The National Professional Standards Review Council shall provide for the preparation and distribution, to each Professional Standards Review Organization and to each other agency or person performing review functions with respect to the provision of health care services under this chapter, of appropriate materials indicating the regional norms to be utilized pursuant to this part. Such

data concerning norms shall be reviewed and revised from time to time. The approval of the National Professional Standards Review Council of norms of care, diagnosis, and treatment shall be based on its analysis of appropriate and adequate data.

(2) Each review organization, agency, or person referred to in paragraph (1) shall utilize the norms developed under this section as a principal point of evaluation and review for determining, with respect to any health care services which have been or are proposed to be provided, whether such care and services are consistent with the criteria specified in section 1320c-4(a)(1) of this title.

(d)(1) Each Professional Standards Review Organization shall—

(A) in accordance with regulations of the Secretary, specify the appropriate points in time after the admission of a patient for inpatient care in a health care institution, at which the physician attending such patient shall execute a certification stating that further inpatient care in such institution will be medically necessary effectively to meet the health care needs of such patient; and

(B) require that there be included in any such certification with respect to any patient such information as may be necessary to enable such organization properly to evaluate the medical necessity of the further institutional health care recommended by the physician executing such certification.

(2) The points in time at which any such certification will be required (usually, not later than the 50th percentile of length-of-stay for patients in similar age groups with similar diagnosis) shall be consistent with and based on professionally developed norms of care and treatment and data developed with respect to length of stay in health care institutions of patients having various illnesses, injuries, or health conditions, and requiring various types of health care services or procedures.

42 USC 1320c-7.

(a) Except as provided for in section 1320c-8 of this title, no Federal funds appropriated under any subchapter of this chapter (other than subchapter V) for the provision of health care services or items shall be used (directly or indirectly) for the payment, under such subchapter or any program established pursuant thereto, of any claim for the provision of such services or items, unless the Secretary, pursuant to regulation determines that the claimant is without fault if—

(1) the provision of such services or items is subject to review under this part by any Professional Standards Review Organization, or other agency; and

(2) such organization or other agency has, in the proper exercise of its duties and functions under or consistent with the purposes of this part, disapproved of the services or items giving rise to such claim, and has notified the practitioner or provider who provided or proposed to provide such services or items and the individual who would receive or was proposed to receive such services or items of its disapproval of the provision of such services or items.

(b) Whenever any Professional Standards Review Organization, in the discharge of its duties and functions as specified by or pursuant to this part, disapproves of any health care services or items furnished or to be furnished by any practitioner or provider, such organization shall, after notifying the practitioner, provider, or other organization or agency of its disapproval in accordance with subsection (a) of this section, promptly notify the agency or organization having responsibility for acting upon claims for payment for or on account of such services or items.

42 USC 1320c-8.

(a) Any beneficiary or recipient who is entitled to benefits under this chapter (other than subchapter V) or a

provider or practitioner who is dissatisfied with a determination with respect to a claim made by a Professional Standards Review Organization in carrying out its responsibilities for the review of professional activities in accordance with paragraphs (1) and (2) of section 1320c-4(a) of this title shall, after being notified of such determination, be entitled to a reconsideration thereof by the Professional Standards Review Organization and, where the Professional Standards Review Organization reaffirms such determination in a State which has established a Statewide Professional Standards Review Council, and where the matter in controversy is $100 or more, such determination shall be reviewed by professional members of such Council and, if the Council so determined, revised.

(b) Where the determination of the Statewide Professional Standards Review Council is adverse to the beneficiary or recipient (or, in the absence of such Council in a State and where the matter in controversy is $100 or more), such beneficiary or recipient shall be entitled to a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title, and, where the amount in controversy is $1,000 or more, to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title. The Secretary will render a decision only after appropriate professional consultation on the matter.

(c) Any review or appeals provided under this section shall be in lieu of any review, hearing, or appeal under this chapter with respect to the same issue.

42 USC 1320c-9.

(a)(1) It shall be the obligation of any health care practitioner and any other person (including a hospital or other health care facility, organization, or agency) who provides health care services for which payment may be made (in whole or in part) under this chapter, to assure that services or items ordered or provided by such practitioner or person to beneficiaries and recipients under this chapter—

(A) will be provided only when, and to the extent, medically necessary; and

(B) will be of a quality which meets professionally recognized standards of health care; and

(C) will be supported by evidence of such medical necessity and quality in such form and fashion and at such time as may reasonably be required by the Professional Standards Review Organization in the exercise of its duties and responsibilities;

and it shall be the obligation of any health care practitioner in ordering, authorizing, directing, or arranging for the provision by any other person (including a hospital or other health care facility, organization, or agency) of health care services for any patient of such practitioner, to exercise his professional responsibility with a view to assuring (to the extent of his influence or control over such patient, such person, or the provision of such services) that such services or items will be provided—

(D) only when, and to the extent, medically necessary; and

(E) will be of a quality which meets professionally recognized standards of health care.

(2) Each health care practitioner, and each hospital or other provider of health care services, shall have an obligation, within reasonable limits of professional discretion, not to take any action, in the exercise of his profession (in the case of any health care practitioner), or in the conduct of its business (in the case of any hospital or other such provider), which would authorize any individual to be admitted as an inpatient in or to continue as an inpatient in any hospital or other health care facility unless—

(A) inpatient care is determined by such practitioner and by such hospital or other provider, consistent with professionally recognized health care standards, to be medically necessary for the proper care of such individual; and

(B)(i) the inpatient care required by such individual cannot, consistent with such standards, be provided more economically in a health care facility of a different type; or

(ii) (in the case of a patient who requires care which can, consistent with such standards, be provided more economically in a health care facility of a different type) there is, in the area in which such individual is located, no such facility or no such facility which is available to provide care to such individual at the time when care is needed by him.

(b)(1) If after reasonable notice and opportunity for discussion with the practitioner or provider concerned, any Professional Standards Review Organization submits a report and recommendations to the Secretary pursuant to section 1320c-6 of this title (which report and recommendations shall be submitted through the Statewide Professional Standards Review Council, if such report and recommendations together with any additional comments and recommendations thereon as it deems appropriate) and if the Secretary determines that such practitioner or provider, in providing health care services over which such organization has review responsibility and for which payment (in whole or in part) may be made under this chapter has—

(A) by failing, in a substantial number of cases, substantially to comply with any obligation imposed on him under subsection (a) of this section, or

(B) by grossly and flagrantly violating any such obligation in one or more instances,

demonstrated an unwillingness or a lack of ability substantially to comply with such obligations, he (in addition to any other sanction provided under law) may exclude (permanently for such period as the Secretary may prescribe) such practitioner or provider from eligibility to provide such services on a reimbursible basis.

(2) A determination made by the Secretary under this subsection shall be effective at such time and upon such

reasonable notice to the public and to the person furnishing the services involved as may be specified in regulations. Such determination shall be effective with respect to services furnished to an individual on or after the effective date of such determination (except that in the case of institutional health care services such determination shall be effective in the manner provided in subchapter XVIII of this chapter with respect to terminations of provider agreements), and shall remain in effect until the Secretary finds and gives reasonable notice to the public that the basis for such determination has been removed and that there is reasonable assurance that it will not recur.

(3) In lieu of the sanction authorized by paragraph (1), the Secretary may require that (as a condition to the continued eligibility of such practitioner or provider to provide such health care services on a reimbursable basis) such practitioner or provider pay to the United States, in case such acts or conduct involved the provision or ordering by such practitioner or provider of health care services which were medically improper or unnecessary, an amount not in excess of the actual or estimated cost of the medically improper or unnecessary services so provided, or (if less) $5,000. Such amount may be deducted from any sums owing by the United States (or any instrumentality thereof) to the person from whom such amount is claimed.

(4) Any person furnishing services described in paragraph (1) who is dissatisfied with a determination made by the Secretary under this subsection shall be entitled to reasonable notice and opportunity for a hearing thereon by the Secretary to the same extent as is provided in section 405(b) of this title, and to judicial review of the Secretary's final decision after such hearing as is provided in section 405(g) of this title.

• • •

42 USC 1320c-12.

(a)(1) There shall be established a National Professional Standards Review Council (hereinafter in this sec-

tion referred to as the "Council") which shall consist of eleven physicians, not otherwise in the employ of the United States, appointed by the Secretary without regard to the provisions of Title 5 governing appointments in the competitive service.

• • •

(c) The Council is authorized to utilize, and the Secretary shall make available, or arrange for, such technical and professional consultative assistance as may be required to carry out its functions, and the Secretary shall, in addition, make available to the Council such secretarial, clerical and other assistance and such pertinent data prepared by, for, or otherwise available to, the Department of Health, Education, and Welfare as the Council may require to carry out its functions.

• • •

(e) It shall be the duty of the Council to—

(1) advise the Secretary in the administration of this part;

(2) provide for the development and distribution, among Statewide Professional Standards Review Councils and Professional Standards Review Organizations of information and data which will assist such review councils and organizations in carrying out their duties and functions;

(3) review the operations of Statewide Professional Standards Review Councils and Professional Standards Review Organizations with a view to determining the effectiveness and comparative performance of such review councils and organizations in carrying out the purposes of this part; and

(4) make or arrange for the making of studies and investigations with a view to developing and recommending to the Secretary and to the Congress measures designed more effectively to accomplish the purposes and objectives of this part.

42 USC 1320c-16.

• • •

(c) No doctor of medicine or osteopathy and no provider (including directors, trustees, employees, or officials thereof) of health care services shall be civilly liable to any person under any law of the United States or of any State (or political subdivision thereof) on account of any action taken by him in compliance with or reliance upon professionally developed norms of care and treatment applied by a Professional Standards Review Organization (which has been designated in accordance with section 1320c-1(b)(1)(A) of this title) operating in the area where such doctor of medicine or osteopathy or provider took such action but only if—

(1) he takes such action (in the case of a health care practitioner) in the exercise of his profession as a doctor of medicine or osteopathy (or in the case of a provider of health care services) in the exercise of his functions as a provider of health care services, and

(2) he exercised due care in all professional conduct taken or directed by him and reasonably related to, and resulting from, the actions taken in compliance with or reliance upon such professionally accepted norms of care and treatment.